

AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings include a change to Fig. 1D (adding element #211 and the addition of Fig. 5W).

These sheets, which include Figs. 1D-1E and 5T-5W, replace the original sheets containing Figs. 1D-1E and 5T-5V.

Attachment: 2 Replacement Sheets

REMARKS

Claims 12-35 are pending in the present application. Claim 12 is amended to recite that the conduit is removed after the channel has healed in an open position. Support for this amendment may be found in, for example, paragraph [00117].

Claims 15 and 18 are amended to recite proper Markush group language. Claim 35 is newly added. Support for this added claim may be found in Fig. 5V and paragraph [0130].

Applicant believes that no new matter is added by way of this amendment.

Concerning the drawings

Applicant submits amended drawings based on discussions with the Examiner and requests entry of the attached replacement drawings.

The attached sheets of drawings includes a change to Fig. 1D (adding element #211 representing imaging as disclosed in paragraphs [0016], [0040], and [0061]). The attached sheets also include the addition of Fig. 5W showing a plug 573 as disclosed in paragraph [00117].

Applicant notes that the specification is amended to reflect the amended drawings.

Interview Summary

Applicant's attorney wishes to express gratitude to the Examiner for the telephone interview of February 27, 2006. The participants included applicant's representative, Sanjay Bagade and Examiner David Shay.

No exhibit was shown.

At this interview, the parties discussed the objection to the drawings.

No agreement was reached.

Objection to the Drawings

The Office Action objected to the drawings stating that the solid plug, the imaging methods selected from radiography, computer tomography, ultrasound, Doppler, MRI, PET

and acoustic imaging, the one way valve, and the self cleaning mechanism must be shown in the drawings or the feature cancelled from the claims.

Applicant amended the drawings to show imaging as recited in the claim. Applicant added Fig. 5W to show the solid plug.

Applicant believes the objection to the drawings based on the one way valve, and the self cleaning mechanism are incorrect.

Applicant notes that the one-way valve is found in Fig. 5U. The text accompanying Fig. 5U (paragraph [[00129]]) clearly discloses “a variation of the device having a one-way valve 570.”

Applicant also notes that the self cleaning mechanism is shown in Fig. 5J. The text accompanying Fig. 5J (paragraph [00122]) clearly discloses that “in this example, the self cleaning mechanism is a floating ball bearing 532.”

35 USC §112 – Claims 33 and 34

The Office Action rejected claims 33 and 34 under 35 USC §112, first paragraph, as failing to comply with the written description requirement. The Office Action asserted that the originally filed disclosure is silent on the manner in which data is manipulated to “determine the degree of collateral ventilation of the lung” or the construction of the self-clearing mechanism. Applicant disagrees.

Regarding the manner in which data is manipulated to “determine the degree of collateral ventilation of the lung”, applicant refers to paragraph [0064]. This paragraph recites that a device 212 may comprise a probe 216 configured to collect data within the lung. The probe 216 may also simply consist of a channel that transmits signals outside of the lung. The device delivers a burst of fluid, through the fluid delivery member 214 and subsequently uses the probe 216 to measure characteristics such as pressure, flow, or return volume to determine the degree of collateral ventilation. The term fluid is intended to include, air or a gas, such as oxygen, etc. For example, if the air sacs are diseased (as shown in figure 1C), the forced fluid will escape/disperse through another air sac due to the collateral ventilation of the air sacs. As a result, the probe 216 may fail to record any increase in pressure, volume, flow, or any other characteristic of the fluid at the site. Another variation of the invention includes using the fluid delivery member 214 to add or remove

fluid distally to the occluded segment and using the probe 216 to monitor flow or pressure changes in the area. For example, if after adding/removing fluid the pressure in the occluded segment fails to build/drop, the assumption may be made that the gas is being collaterally vented through diseased air sacs. Accordingly, applicant believes this rejection should be withdrawn.

Applicant further notes that the construction of the self-clearing mechanism (also discussed above is found in Fig. 5J and paragraph [00122].

Applicant notes that the above was discussed in the Telephone Interview of February 27, 2006 during which the Examiner indicated that the rejection would be withdrawn.

35 USC §112 – Claims 15, 18, 22, 24-27, and 29-33

The Office Action rejected claims 15, 18, 22, 24-27, and 29-33 under 35 USC §112, first paragraph, as failing to comply with the written description requirement.

The Office Action indicated that claims 15 and 18 failed to recite proper Markush group language. In response, Applicant amended claims 15 and 18.

The Office Action indicated that claims 22, 24-27 and 29-33 are indefinite as they fail to further limit the claim from which they depend as they merely recite particular structures that do not manipulatively affect the method.

Applicant disagrees with this rejection. First, the methods in each claim are further limited by the specific element recited in the dependent claim. For example, claim 21 recites providing a medication to the lung where the medication inhibits the healing process of the lung. Claim 22 further limits this method by requiring that the medication is a steroid – a clear limitation from claim 21. In essences, claim 22 recites providing a steroid to the lung where the steroid inhibits the healing process of the lung. This manipulatively affects the method. Claims 24-27 each recite additional elements that further limit the methods from which they depend. Based on this alone, applicant requests withdrawal of this rejection.

Second, applicant requests that the Office Action provides some statutory or legal basis for the standard being set forth in this rejection.

Double Patenting Rejections – General Comment

The Office Action rejected claims 12-34 over various claims in US Patents 6,488,673 and 6,634,363. Applicant notes that at the end of December, 2003, Broncus Technologies, Inc. formed a separate entity, Asthmatx, Inc. using certain assets related to Broncus' asthma related procedures and devices. The '673 and '363 patents were assigned to Asthmatx Inc.

Double Patenting Rejections over US Patent No. 6,488,673

The Office Action rejected claims 12-34 under judicial double patenting over claims 1-17 of US Patent No. 6,488,673. Applicant disagrees.

Claims 1 and 14 of the '673 patent recites a method, comprising inserting an apparatus into an airway of a lung; and damaging lung cells with the apparatus to cause fibrosis to stiffen the airway so as to increase gas exchange performed by the lung.

Applicant notes that the subject claims involve creation of an extra-anatomic path to allow trapped gasses to exit from the lung. Applicant's claims are clearly patentably distinct and do not speak to creation of fibrosis to stiffen the airway. The '673 patent teaches that fibrosis is the natural formation of fibrotic tissue, such as scar tissue, in response to trauma or injury. Fibrosis is the formation of fibrous or fibrotic tissue as a reparative or reactive process. Applicant's claim requires the use of the conduit to prevent the opening from healing closed. More specifically, the '673 patent teaches against formation of an extra-anatomic passage as noted in Col. 9, lines 20-22 (where it teaches against defining a new cavity in the airway wall).

Claim 8 of the '673 patent recites a method, comprising inserting an apparatus into an airway of a lung; and damaging tissue in the lung with the apparatus to increase gas exchange performed by the lung. Again, the '673 patent teaches increasing gas exchange by stiffening, strengthening, or destroying airway smooth muscle tone of at least one airway of a lung. (See '673 patent col. 2 line 66 through col. 3, line 2). The '673 patent further teaches that by strengthening the airway walls of an emphysematous lung, the balance of forces during exhalation is shifted back toward keeping the airways open. In short, stiffening the airway wall helps prevent airway collapse during exhalation, which will thus result in an increase in airflow and gas exchange. (See '673 patent, col. 8, lines 43-48). Again, as noted above, the '673 patent teaches against defining a new cavity in the airway wall. Clearly, applicant's

claims, which requires creation and maintenance of an extra-anatomic passage or channel, are patentably distinct.

Claim 15 of the '673 patent recites method, comprising inserting an apparatus into an airway of a lung; and destroying airway smooth muscle tone with the apparatus to increase gas exchange performed by the lung. Again, destroying airway smooth muscle to increase gas exchange of a lung is patentably distinct from applicant's claim of creating an extra-anatomic passage. Destruction of the smooth muscle tone refers to ability of the smooth muscle of the airway to respond to signals that trigger the airway smooth muscle to continually and partially contract. (See e.g., '673 patent col. 9, lines 23-43.)

Claim 17 of the '673 patent recites a method of increasing gas exchange performed by a lung, comprising inserting an apparatus into an airway of a lung; and damaging airway tissue with the apparatus to thicken a wall of the airway.

As noted above, applicant's claim does not involve thickening the airway wall.

In view of the above, applicant submits that the claims in the subject application are patentably distinct over claims 1-17 of the '673 patent and applicant requests withdrawal of this rejection.

Double Patenting Rejections over US Patent No. 6,599,311

The Office Action rejected claims 12-34 under judicial double patenting over claims 58-72 of US Patent No. 6,599,311. Applicant disagrees.

Claim 58 recites a method for minimally invasively or non-invasively treating a lung having at least an emphysematous portion comprising the step of improving a pulmonary function of at least a first portion of the lung by reducing a volume of a second portion of the lung while maintaining communication between the first portion and the second portion.

Claim 68 recites a lung volume reduction device kit comprising the lung volume reduction device of claim 1 (where claim 1 recites an anchor, a connector and a cord); and a bronchoscope.

Claim 72 recites a method for preparing the lung volume reduction device of claim 1 for use in a medical procedure comprising the steps of sterilizing the lung volume reduction device; and packaging the lung volume reduction device.

Applicant notes that claims 59-67 and 69-71, all ultimately depend from either claim 58 or 68.

In view of the above independent claims, applicant submits that all of the claims in '311 patent have little if any relation to applicant's claim, which recites a method of altering gaseous flow in a lung, comprising: locating a site in the lung for creating a collateral channel; creating the channel in an airway wall of the lung; temporarily inserting a conduit into channel; and subsequently removing the conduit.

In view of the above, applicant believe this rejection is improper and request withdrawal of this rejection.

Double Patenting Rejections over US Patent No. 6,610,053

The Office Action rejected claims 12-34 under judicial double patenting over claims 1-17 of US Patent No. 6,610,053. Applicant notes that this patent is used in 3 rejections in the same Office Action. This patent is assigned to BioLase Technology, Inc. Moreover, the '053 claims relates to: a method of mechanically removing portions of a target surface; a method of providing electromagnetically induced mechanical cutting forces onto a target surface to thereby remove portions of the target surface; and a method of controlling a cutting efficiency of an electromagnetically induced mechanical cutter.

During the interview of February 27, 2006, applicant's attorney and the Examiner noted that this rejection appears to be in error and should be withdrawn.

Double Patenting Rejections over US Patent No. 6,692,494

The Office Action rejected claims 12-34 under judicial double patenting over claims 1-74 of US Patent No. 6,692,494. Applicant disagrees.

However, in view of the fact that the '494 is in the chain of prior applications applicant shall submit a proper terminal disclaimer on the indication that the claims will be otherwise allowable.

Double Patenting Rejections over US Patent No. 6,634,363

The Office Action rejected claims 12-34 under judicial double patenting over claims 1-77 of US Patent No. 6,634,363. The Office Action stated that it is notorious in the art to

provide a stent in a surgically created or enlarged channel in order to prevent the reclosure thereof. Applicant disagrees.

Claim 1 of the '363 patent recites a method for treating a lung having reversible obstructive pulmonary disease comprising the steps of advancing a treatment instrument into the lung; and treating an airway wall of the lung with the instrument to at least reduce the ability of the lung to produce at least one reversible obstructive pulmonary disease symptom.

Applicant's claims recites a method of altering gaseous flow in a lung, comprising: locating a site in the lung for creating a collateral channel; creating the channel in an airway wall of the lung; temporarily inserting a conduit into channel; and subsequently removing the conduit after the channel has healed in an open position. Claim 1 of the '363 patent is clearly patentably distinct from applicant's claim. The '363 patent teaches in col. 1, lines 34-57 that the reversible obstructive pulmonary disease includes asthma and reversible aspects of chronic obstructive pulmonary disease. The '363 patent teaches that the reversible aspects of COPD generally describe excessive mucus production in the bronchial tree. Usually, there is a general increase in bulk (hypertrophy) of the large bronchi and chronic inflammatory changes in the small airways. Excessive amounts of mucus are found in the airways and semisolid plugs of mucus may occlude some small bronchi. Also, the small airways are narrowed and show inflammatory changes. The reversible aspects of COPD include partial airway occlusion by excess secretions, and airway narrowing secondary to smooth muscle contraction, bronchial wall edema and inflation of the airways.

In contrast, applicant's claim creates a channel and then temporarily places an implant in the channel to create an artificial flow-path – this does not affect the ability of the lung to produce any symptom. Instead, it allows for trapped gas to vent from the lung. The Office Action appears to reject applicant's claim based on the mere relation that both acts are performed within the lung. Clearly, creation of an extra-anatomic flowpath is patentably distinct from treating the lung to reduce its ability to produce symptoms of a disease such as bronchoconstriction, mucus production, inflammation and swelling. Applicant further notes that destruction of tissue (as discussed in the subject application) is not reversible.

Claim 57 recites a method for treating a lung having reversible obstructive pulmonary disorder to reduce the lung's ability to produce at least one of symptom of reversible

obstructive pulmonary disease, the method comprising advancing a treatment instrument into the lung; and applying energy to an airway wall of an airway in the lung with the instrument.

Again, claim 57 uses energy to prevent the lung from having the ability to produce a symptom of a disease. This is clearly patentably distinct from creating an extra-anatomic passage in an airway wall.

Applicant notes that claims 2-56 and 58-72 all depend from either claim 1 or 57. In view of the above, applicant submits that the subject claims are patentably distinct from claims 1-72 of the '363 patent and requests withdrawal of this rejection.

**Double Patenting Rejections over copending US Patent Application Nos.
10/978,905, 10/966,644, 10/862,933**

The Office Action rejected claims 12-34 under judicial double patenting over various claims in copending US Patent application Nos. 10/978,905, 10/966,644, and 10/862,933. Applicant disagrees that it is obvious to treat lungs for improper collateral ventilation when diagnosing it.

However, to expedite prosecution, applicant shall submit a proper terminal disclaimer upon the indication that the claims are otherwise allowable.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'S. Bagade', with a horizontal line drawn through it.

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